

JUNE 9, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

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Dear FDA:

Food and Drug Administration guidelines issued April 6, 1999 instituted a "de facto" ban on nonhuman primate xenografts because they would expose patients and the public to "significant infectious disease risk" (Docket No. 99D-0557). But the guidelines failed to address dangers with other species. Transgenic pigs are considered the source animals of choice for xenotransplants despite the existence of over 25 diseases in pigs that can infect humans. Pigs are not safer than nonhuman primates: witness swine influenza, the Porcine Endogenous Retroviruses, paramyxovirus, and the new "Nipah" virus in Malaysia that infected over 250 humans, killed 100, and led to the slaughter of some one million pigs. There are safer, more cost-effective and humane alternatives to xenotransplantation that are not being explored by regulatory authorities. These include investing heavily in preventive medicine programs to reduce the need for transplants of all kinds, and increasing the pool of human organs as many European countries have done through legislative schemes. We respectfully demand that the Department of Health and Human Services ban xenotransplantation, from all nonhuman species immediately.

(15) Sincerely,

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